UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,228	09/24/2004	Yasuhiro Shiomi	512.44300X00	1797

7590 10/20/2006

Antonelli Terry Stout & Krause
1300 North Seventeenth Street
Suite 1800
Arlington, VA 22209

EXAMINER	
ROBINSON, BINTA M	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,228	SHIOMI ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/24/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Inokuchi et. al. (J. of Org. Chem.) Inokuchi et. al. discloses the instant process of producing 2-methyl, 5-ethyl 3-pyridinylaldehyde by reacting 2-methyl, 5-ethyl-3-pyridinylmethanol with a 2,2,6,6-tetramethylpiperidine-oxyl derivative in the presence of sodium bromite. At page 464, Table II, see entry 12. The Inokuchi process anticipates claims 1-4 because a heterocyclic aldehyde which is 2-methyl, 5-ethyl 3-pyridinylaldehyde is produced by reacting 2-methyl, 5-ethyl-3-pyridinylmethanol with a 2,2,6,6-tetramethylpiperidine-oxyl derivative in the presence of sodium bromite.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Inokuchi et. al. (Bull. Chem. Soc.). Inokuchi et. al. discloses the instant process of producing the compound of 2i by oxidizing the compound of 1i by an N-oxyl-5-Bu4NBr3 system that involves the formation of a hypobromite species which is reacted with a compound of formula 5 which gives rise to N-oxoammonium salts that are responsible for the oxidation of the substrates in the organic phase to produce the compound of 2i. At page 798, column 2, entry 9, see the instant process. Inokuchi et. al. also discloses the instant process of producing the compound of 2j by oxidizing the compound of 1j by an N-oxyl-5-Bu4NBr3 system that involves the formation of a hypobromite species which is

reacted with a compound of formula 5 which gives rise to N-oxoammonium salts that are responsible for the oxidation of the substrates in the organic phase to produce the final product of compound 2j. At page 798, column 2, Table 2, entry 10, see the instant process. Also see page 797, column 2, lines 1-8 regarding the hypobromite species and the oxidation system. The Inokuchi process anticipates claims 1-4 because a heterocyclic aldehyde which is 2-methyl, 5-ethyl 3-pyridinylaldehyde is produced by reacting 2-methyl, 5-ethyl-3-pyridinylmethanol with a 2,2,6,6-tetramethylpiperidine-oxyl derivative in the presence of sodium bromite. Additionally, in an alternative process, see entry 9, p-pyridinylaldehyde is produced by oxidizing para-pyridinylmethanol with the N-Oxyl5-Bu4NBr3 system which anticipates claims 1-4.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the product compounds wherein the heterocyclic moiety of the heterocylic aldehyde is 3-pyridine, 6-methyl-2-pyridine, or 3-thiopehene, does not reasonably provide enablement for making all heterocyclic aldehydes with the instant process. The specification does not enable any skilled organic chemist to use the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection have been summarized above.

a) Determining if any particular claimed compounds with heterocyclic moieties equal to heterocyclic rings other than 3-pyridine, 6-methyl-2-pyridine, or 3-thiopehene could be made by the instant process would require synthesis of all of the products claimed. Considering the large number of compounds to be made this is a large quantity of experimentation. b) The direction concerning the claimed processes of making the instant compounds is found in examples 1-7 and comparative examples 1—3 on pages 36-40 of the specification c) In the instant case, none of the working examples contains any processes whereby heterocyclic aldehyde compounds with heterocyclic rings other than 3-pyridine, 6-methyl-2-pyridine, or 3-thipehene are made. d) The nature of the invention is a process of making all heterocyclic aldehyde compounds by reacting a compound having a hydroxymethyl group bonded to a carbon atom of a heterocyclic ring with a hyphalogenous acid salt. In view of the unpredictability of synthesizing these varied compounds with divergent chemical properties, the skilled organic chemist would indeed question the inclusion of such diverse rings, commensurate in scope with these claims in the products being claimed.

e) The pyridine ring in the working examples, and the pyrimidine ring, and the pyrazine ring of the rejected compounds are strongly basic, basic, and weakly basic respectively. There is no reasonable basis for the assumption that the myriad of compounds produced by the instant process will all share the same chemical properties. The diverse claimed fused heterocyclic rings are chemically non-equivalent and there is no basis in the prior art for assuming in the non-predictable art of organic chemistry that structurally dissimilar compounds will have such activity, *In re Surrey* 151 USPQ 724

(compounds actually tested which demonstrated the asserted psychomotor stimulatory and anti-convulsant properties were those having the 3,4-dichlorophenyl substituent at the 2-position on the thiazolidone nucleus not sufficient for enablement of any heterocyclic radical at the same position). *In re Fouche*, 169 USPQ 429 at 434 (a Markush group including both aliphatic and heterocyclic members not enabled for the use of those compounds within the claim having heterocyclic moieties.) *In re CAVALLITO AND GRAY*, 127 USPQ 202 (claims covering several hundred thousand possible compounds, of which only thirty are specifically identified in appellants' application, not enabled unless all of the thirty specific compounds disclosed had equal hypotensive potency because that fact would strongly indicate that the potency was derived solely from the basic structural formula common to all of them. A wide variation in such potency would suggest that it was due in part to the added substituents and might be eliminated or even reversed by many of the possible substituents which had not been tried.)

f) The artisan using Applicants' invention would be an organic chemistry with a Master's or PhD degree and several years of experience. He would be unaware of how to predict *a priori* how to obtain all heterocyclic aldehydes with the instant process. In view of the divergent rings with varied basicity, steric hindrance, and polarisability, the skilled organic chemist would indeed question the inclusion of such varied rings, commensurate in scope with these claims. See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). h) The breadth of the claims includes all of millions of

heterocyclic aldehyde compounds which are formed. Thus, the scope is very broad. The present claims embrace various heterocyclic radicals, which are not art-recognized as equivalent. The specific compounds made are not adequately representative of the compounds embraced by the extensive Markush groups instantly claimed.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

The IDS filed 9/24/04 has been considered. The references that have been lined through will not be considered until provided to the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Thomas McKenzie can be reached on 571-272-0670.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR
October 13, 2006

THOMAS MCKENZIE, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600